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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,356	11/25/2003	Antonio Cutando Soriano	285.1001US	4724

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485 Seventh Avenue
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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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07/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,356	SORIANO ET AL.	
	Examiner	Art Unit	
	Frederick Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Previous Rejections

Unless specifically repeated/maintained infra, all previous rejections are withdrawn.

Election by Original Presentation

Newly submitted claims 9-12 are directed to an invention that is independent or distinct from the invention originally claimed and would have been restricted therefrom had they been originally submitted, because the product as claimed in claims 1-8 can be used in a materially different process of using that product, i.e. for purely cosmetic purposes such as cleaning, whitening or otherwise improving the appearance of teeth in healthy individuals. See MPEP § 806.05(h).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 9-12 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

Art Unit: 1614

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Written Description Rejection (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support is seen in the specification as originally filed for reciting a lower limit of melatonin of "more than 2%". The specification discloses a lower limit of "2" per se, but not "more than 2".

Anticipation Rejection

1) Claims 1, 3 and 4 were rejected under 35 USC 102(e) as being anticipated by Zuckerman (USP 6,998,112).

This rejection is maintained and is applicable to newly added claim 8 as well.

Contrary to applicant's arguments, patentee discloses the use of "more than 2 percent" melatonin, as is implicit in the disclosure of "substantially" 2 percent at column 5, line 25. (Note

Art Unit: 1614

also that a prior art disclosure of "2" anticipates a value of "more than 2" insofar as there will always be some inherent statistical variation due to slight errors in measurement, making delineation of the two effectively impossible from a practical standpoint).

Note also that newly added claim 8 is anticipated for the same reasons given previously. Benzoic acid is disclosed in the form of its sodium salt (column 1, line 45). Note also that essential oils are disclosed at column 2, line 33 and column 4, line 39, at least.

2) Claims 1, 3, 4 and 6 were rejected under 35 USC 102(b) as being anticipated by Masterson (USP 6,200,550).

This rejection is maintained and is applicable to newly added claim 8 as well.

Applicant argues that the prior art does not disclose a specific percentage of melatonin since the range of 0.1 to 20 percent given at the first paragraph of column 7 relates to the preferred species tocopheryl acetate and B-carotene only. The examiner does not agree with this interpretation since it is a literal reading based purely on the word-for-word construction of the sentence which ignores the overall context in which the statement was made. It is reasonably clear from the overall discussion of "antioxidants" generally in the entire paragraph bridging the bottom column 6 and the top of column 7 that the ranges are applicable to antioxidants in general, with tocopheryl acetate and B-carotene being cited for the purposes of exemplification.

Again, note also that newly added claim 8 is anticipated for the reasons given previously. Sorbic acid is used in working example 4 (column 12).

Obviousness Rejection

Claims 1-6 were rejected under 35 USC 103(a) as being unpatentable over Rajaiah et al (USP 6,509,007) in view of Masterson et al (USP 6,200,550).

This rejection is maintained and is applicable to newly added claims 7 and 8 as well.

Applicant urges that the references are not combinable since “the coating on teeth created by the products described in the Rajaiah patent may interfere with availability and local effects of the antioxidant Coenzyme Q10 of the Masterson patent.” The examiner does not agree; this is mere speculation on applicant’s part. In point of fact, Rajaiah et al teach that their coatings “provide[s] sufficient substantivity to provide sustained release of an oral care active” (column 1, lines 48-51). Thus, if anything, one would presume this would actually improve the availability of Coenzyme Q10, given that it is hydrophobic like polybutene.

Action is Final, Necessitated by Amendment

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1614

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

